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TAROLLI, SUNDHEIM, COVELL & TUMMINO L.L.P. 1300 EAST NINTH STREET, SUITE 1700			EXAMINER	
			MEHTA, PARIKHA SOLANKI	
CLEVEVLAND, OH 44114			ART UNIT	PAPER NUMBER
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

	Application No.	Applicant(s)			
	10/509,509	ROBERTSON ET AL.			
Office Action Summary	Examiner	Art Unit			
	PARIKHA S. MEHTA	3737			
The MAILING DATE of this communication app	ears on the cover sheet with the c	orrespondence address			
Period for Reply					
A SHORTENED STATUTORY PERIOD FOR REPLY WHICHEVER IS LONGER, FROM THE MAILING DA. - Extensions of time may be available under the provisions of 37 CFR 1.1: after SIX (6) MONTHS from the mailing date of this communication. - If NO period for reply is specified above, the maximum statutory period variety exilure to reply within the set or extended period for reply will, by statute. Any reply received by the Office later than three months after the mailing earned patent term adjustment. See 37 CFR 1.704(b).	ATE OF THIS COMMUNICATION 36(a). In no event, however, may a reply be tim vill apply and will expire SIX (6) MONTHS from a cause the application to become ABANDONE	N. nely filed the mailing date of this communication. D (35 U.S.C. § 133).			
Status					
1)⊠ Responsive to communication(s) filed on <u>16 M</u>	arch 2009				
	action is non-final.				
· -					
closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213.					
Disposition of Claims					
4)⊠ Claim(s) <u>1-22</u> is/are pending in the application.					
4a) Of the above claim(s) is/are withdrawn from consideration.					
5) Claim(s) is/are allowed.					
6) Claim(s) <u>1-22</u> is/are rejected.					
7) Claim(s) is/are objected to.					
8) Claim(s) are subject to restriction and/o	r election requirement.				
Application Papers					
9)⊠ The specification is objected to by the Examine	r.				
10) The drawing(s) filed on is/are: a) accepted or b) objected to by the Examiner.					
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).					
Replacement drawing sheet(s) including the correct	ion is required if the drawing(s) is obj	ected to. See 37 CFR 1.121(d).			
11)☐ The oath or declaration is objected to by the Ex	aminer. Note the attached Office	Action or form PTO-152.			
Priority under 35 U.S.C. § 119					
12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a)☐ All b)☐ Some * c)☐ None of:					
a)					
2. Certified copies of the priority documents have been received in Application No					
3. Copies of the certified copies of the priority documents have been received in this National Stage					
application from the International Bureau (PCT Rule 17.2(a)).					
* See the attached detailed Office action for a list of the certified copies not received.					
	·				
Attachment(s)					
1) Notice of References Cited (PTO-892)	4) 🔲 Interview Summary				
2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) Information Disclosure Statement(s) (PTO/SB/08)	Paper No(s)/Mail Da 5) Notice of Informal P				
S) Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date 5) Notice of Informal Patent Application 6) Other:					

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DETAILED ACTION

Specification

1. The title of the invention is not descriptive. A new title is required that is clearly indicative of the novel feature(s) of the invention to which the claims are directed.

Claim Objections

2. Claims 1-22 are objected to because of the following informalities:

In line 3 of claim 1, "for sensing" should be replaced with "configured to sense".

In line 4 of claim 1, "for collecting" should be replaced with "configured to collect".

In line 2 of claim 3, "for supplying" should be replaced with "configured to supply".

Claim 8 recites "focusing means", which is improper means plus function language; for the purposes of further examination herein, the claim will not be treated as properly invoking 35 U.S.C. 112, 6th paragraph.

In line 1 of claim 9, "are" should be corrected to read "is".

In line 2 of claim 10, "comprise" should be corrected to read "comprises".

Appropriate correction is required.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 1-22 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claim 1 recites "scanning means for causing a scan of a target area of a patient", wherein such recitation constitutes an invocation of 35 U.S.C. 112, 6th paragraph. While the specification sets forth

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scanning means for rotating the collection path (i.e., a rotating mirror), the specification does not describe configuration or arrangement of such scanning means that would render it capable of "causing a scan" (emphasis added). As such, one of ordinary skill in the art would not be reasonably apprised of how to make and use the claimed invention based on what is provided by the present disclosure.

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Claim 6 recites the collected radiation as having a Bessel sensitivity profile. The present specification describes the inventive apparatus as having a Bessel sensitivity profile (paragraph 9), but does not describe or disclose the actual radiation as having such profile. Furthermore, the disclosure lacks any description of the collected radiation beam (i.e., the beam at point of contact with the collector) having a Bessel sensitivity profile. As shown in Figure 13, the Bessel beam is converted to a Gaussian beam prior to reaching the collector, and therefore the collected radiation beam in that embodiment has a Gaussian profile. As such, the disclosure is not enabling for the collector to be configured to collect a beam having a Bessel sensitivity profile. Accordingly, a person of ordinary skill in the art would not be reasonably apprised of how to make and use the present invention according to the provided disclosure. In view of the degree of non-enablement of the features recited in claims 6 and 7, they cannot be further treated in view of the prior art herein.

Claim 21 sets forth the non-uniformity of the sensitivity profile of the collection path as being based on "known changes in a location of a focal spot of the scanning means along the collection path". The basing of the non-uniformity of the profile of the collection path on any feature related to the focal spot of the scanning means is not described in the disclosure. As such, a skilled artisan would not be reasonably apprised of how to make and use the claimed invention. Due to the lack of support in the disclosure, the claim cannot be treated further in view of the prior art.

- 5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

 The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
- 6. Claims 1-22 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential elements, such omission amounting to a gap between the elements. See MPEP § 2172.01. The omitted elements are: elements configured to generate and display an image as set forth in the preamble of claim 1. The present claims set forth nothing more than elements configured to collect and detect radiation, without the radiation source and imaging elements required to render the system an "imager". Similarly, claim 13 sets forth function unsupported by structure to produce such function (i.e.,

the function of forming an image without reciting any elements such as an image processor or display to achieve such image formation).

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7. Claims 4-7, 9-12, 14-16, 18, 20 and 21 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claims 4, 6 and 7, it is unclear what structural limitation is being set forth by the recitation "is such that". For the purposes of further examination herein, such recitation is considered to be nothing more than a recitation of intended use unsupported by structure to produce such function.

In claim 5, it is unclear how mere arrangement (i.e., placement) of the feedhorn enables it to convert a radiation beam into a waveguide mode. For the purposes of further examination herein, this limitation is interpreted to constitute nothing more than a functional recitation unsupported by structure to produce such function.

In claim 9, it is unclear what is being set forth by the recitation "sweep the collection path through 360°". Furthermore, the specification describes the scanning means as being rotated by a motor separate from the scanning means, but does not describe the scanning means itself as being operable rotate (i.e., "sweep"). As such, it is unclear how the scanning means can be operable to rotate/sweep along any path

Claims 11 and 12 recite "line indexing means for moving the collection path", wherein such recitation constitutes an invocation of 35 U.S.C. 112, 6th paragraph. While the specification describes steps for indexing in paragraph 47, the specification fails to set forth any specific structure configured to achieve such steps. It has previously been held that, if one employs means plus function in a claim, one must set forth in the specification an adequate disclosure showing what is meant by that language. If an application fails to set forth an adequate disclosure, the applicant has failed to particularly point out and distinctly claim the invention (*In re Donaldson Co.*, 16 F.3d 1189, 1195, 29 USPQ2d 1845, 1850 (Fed. Cir. 1994) (in banc)).

Claim 12 recites "the first axis" without sufficient antecedent basis.

Claims 14-16 recite "the imager" as an element separate from the collector and detector. However, claim 1 sets forth "the imager" as comprising both the collector and detector. As such, the claims do not clearly set forth the structural relationship between the imager, the collector, and the detector.

Claim 15 recites "the scanning path of the imager" without sufficient antecedent basis.

In line 2 of claim 16, it is unclear what is being recited by "them".

Claim 16 recites "the range of subcutaneous body temperatures to be imaged" without sufficient antecedent basis.

In claim 16, it is unclear how the "two calibration loads" recited therein relate to the at least one calibration load set forth in claim 14.

In claim 18, it is unclear what is being set forth by "so as to align with".

In claim 20, it is unclear what is being set forth by "given".

Claim 21 recites "the defined sensitivity profile of the collection path" without sufficient antecedent basis. Claim 1 only sets forth a defined sensitivity profile for the collected radiation.

Claim Rejections - 35 USC § 103

- 8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
 - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- 9. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).
- 10. Claims 1-4, 6, 8-10, 20 and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Edrich (US Patent No. 4,407,292), hereinafter Edrich ('292), of record, in view of Volkov et al (US Patent No. 6,777,684), hereinafter Volkov ('684).

Regarding claims 1, 4, 6 and 22, Edrich ('292) teaches a non-contact passive medical scanning imager including a detector 5, a collector 2, and scanning means 1. Examiner notes that the collected radiation of Edrich ('292) inherently has some sensitivity profile along the collection path, and the recitation of "defined" does not structurally distinguish the recited collector from that of the prior art.

Similarly, the recitation of "substantially" is subjective and open to extremely broad interpretation, and as such the recitation is not given significant patentable weight.

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Edrich ('292) lacks isolation means in the path of the collected radiation for prevented signal leakage from the detector being emitted towards a patient's body. In the same field of endeavor, Volkov ('684) teaches placement of a quasi-optical isolator 21 between the field of view (i.e., the patient's body) and the detector for the purpose of directing the radiation towards the imaging plane, which is interpreted to constitute prevention of signal leakage as claimed (col. 3 line 67 - col. 4 line 3). It would have been obvious to one of ordinary skill in the art at the time of invention to have modified Edrich ('292) to include the isolator of Volkov ('684) and thereby yield the claimed invention, in order to better control the direction of radiation towards the imaging plane.

Regarding claims 2, 4 and 20, Volkov ('684) teaches a corrugated feedhorn (col. 65 lines 55-56), which is known in the art to produce a Gaussian beam (i.e, a beam having a profile which is symmetrical and reduced about a given spot along a collection path).

Regarding claim 3, Edrich ('292) teaches the collector to comprise a waveguide (col. 2 lines 54-55).

Regarding claim 8, the horn of Edrich ('292) is capable of focusing the collected beam onto the detector and therefore constitutes "focusing means".

Regarding claims 9 and 10, the deflector 1 of Edrich ('292) constitutes a reflector, and it is capable of being manually rotated about an arbitrary axis along a complete circular path (i.e., it is "rotatable about one axis" and "operable to sweep a path of 360 degrees"). In claim 10, the recitation "to scan the collection path..." is nothing more than a recitation of intended use, which is not given patentable weight.

11. Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Edrich ('292) and Volkov ('684) as applied to claim 1 above, and further in view of Kool et al (US Patent No. 5,953,644), hereinafter Kool ('644).

Neither Edrich ('292) nor Volkov ('684) teach the feedhorn as arranged to convert a Gaussian beam to a waveguide mode. In the same field of endeavor, Kool ('644) teaches a feedhorn attached to a receiver via a waveguide section 15 (Fig. 1). It would have been obvious to one of ordinary skill in the art at the time of invention to have modified Edrich ('292) and Volkov ('684) to arrange the feedhorn next to a waveguide section as taught by Kool ('644) in order to couple the received radiation to the detector.

12. Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over Edrich ('292) and Volkov ('684) as applied to claim 1 above, and further in view of Huguenin et al (US Patent No. 5,760,397), hereinafter Huguenin ('397), of record.

Neither Edrich ('292) nor Volkov ('684) teach the imager as forming an image from radiation emitted in the range of 90-100 GHz. Edrich ('292) teaches imaging for frequencies between 8-36 GHz (col. 4 lines 56-60). In the same field of endeavor, Huguenin ('397) teaches that it is known that the human body emits radiation in the frequency range of 30 GHz - 300 GHz (col. 1 lines 17-25). It would have been obvious to one of ordinary skill in the art at the time of invention to have modified Edrich ('292) and Volkov ('684) to form images from radiation emitted in the frequency range of 30-300 GHz, which includes 90-100 GHz as claimed, in order to form a more comprehensive image of the radiation emitted by the human subject.

13. Claims 14, 15, 17 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Edrich ('292) and Volkov ('684) as applied to claim 1 above, and further in view of Huguenin et al (US Patent No. 5,047,783), hereinafter Huguenin ('783), of record.

Regarding claims 14 and 15, neither Edrich ('292) nor Volkov ('684) teach at least one calibration load. In the same field of endeavor, Huguenin ('783) teaches that provision of a calibration load in a millimeter wave imaging system is effective to enable noise cancellation for enhancing image resolution (col. 2 lines 8-46). It would have been obvious to one of ordinary skill in the art at the time of invention to have modified Edrich ('292) and Volkov ('684) to include at least one calibration load as taught by Huguenin ('783), in order to achieve noise cancellation.

Regarding claims 17 and 18, neither Edrich ('292) nor Volkov ('684) teach the detector to be linearly polarized. In the same field of endeavor, Huguenin ('783) teaches a linearly polarized detector and associated polarizing element configured to align received with the detector, for the purpose of enabling noise cancellation as discussed for claims 14 and 15. It would have been obvious to one of ordinary skill in the art at the time of invention to have modified Edrich ('292) and Volkov ('684) to employ the linearly polarized detector and polarizer of Huguenin ('783) and thereby yield the claimed invention, in order to achieve noise cancellation.

14. Claims 16 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Edrich ('292), Volkov ('684) and Huguenin ('783) as applied to claim 14 above, further in view of Gasiewski (US Patent No. 5,231,404), hereinafter Gasiewski ('404).

Regarding claim 16, either Edrich ('292), Volkov ('684), nor Huguenin ('783) teach two calibration loads, nor do they teach means for maintaining the loads at different temperatures. In the same problem solving area, Gasiewski ('404) teaches means for calibrating a millimeter wave radiometer (i.e, "detector") comprising two calibration loads of differing temperatures (col. 3 lines 48-54). It would have been obvious to one of ordinary skill in the art at the time of invention to have modified Edrich, ('292), Volkov ('684) and Huguenin ('783) to include the two calibration loads of Gasiewski ('404), as such a modification would require nothing more than the mere combination of known prior art elements to yield predictable results, which has previously been held as obvious and unpatentable (KSR International Co. v. Teleflex Inc., 82 USPQ2d 1385).

Regarding claim 19, neither Edrich ('292) nor Volkov ('684) teach the scanning means as scanning the patient such that the collection path is in the form of a circumference of a notional cylinder at each of a plurality of steps. Edrich ('292) does teach scanning the patient at a plurality of indexed steps (). In the same field of endeavor, Gasiewski ('404) teaches scanning an object by rotating scanning means along a circumferential collection path (Fig. 3). It would have been obvious to one of ordinary skill in the art at the time of invention to have modified Edrich ('292) and Volkov ('684) to include the rotating means of Gasiewski ('404) and thereby yield the claimed invention, as such a modification would require nothing more than the mere combination of known prior art elements to yield predictable results, which has previously been held as obvious and unpatentable (KSR International Co. v. Teleflex Inc, 82 USPQ2d 1385).

Response to Arguments

15. Applicant's arguments with respect to claims 1-22 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to PARIKHA S. MEHTA whose telephone number is (571)272-3248. The examiner can normally be reached on M-F, 8 - 4:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on 571.272.4956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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/BRIAN CASLER/ Supervisory Patent Examiner, Art Unit 3737

/Parikha S Mehta/ Examiner, Art Unit 3737